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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/032,495	01/02/2002	Wen Liang Yan	0249-0002US	7029

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EXAMINER	
LI, QIAN JANICE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/032,495	YAN ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *1-28 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6/11/02* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment and response filed 7/12/04 have been entered. Claims 29 and 31 have been amended. Claims 1-28 and 30 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 29 and 31-33 are under current examination.

Unless otherwise indicated, previous rejections that have been rendered moot in view of the amendment to pending claims will not be reiterated. The arguments in 7/12/04 response would be addressed to the extent that they apply to current rejection.

This application contains claims (1-28, 30) drawn to an invention nonelected without traverse. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

The specification contains sequence disclosures (Figures 6A, 6B, 7, 11) that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2) but are not present in the Sequence Listing and/or identified in the specification by sequence identifier numbers. Applicant must provide sequence identifiers, in the case that these sequences are not included in the original sequence submission, a paper copy and a computer readable copy of the Sequence Listing and a statement that the content of the paper and computer readable copies are

the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). A full response to this Office Action must include a complete response to the requirement for a Sequence Listing.

Claim Rejections - 35 USC § 101 & 112

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 29, 31, 32 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible asserted or a well-established utility, for reasons of record and following.

In the response, applicants argue that human HS cells could be obtained as shown in Lin et al publication, and point to the specification pages 22 and 45, showing that the human oocytes can be activated parthenogenetically. However, it is noted that *Lin et al* publication only show "proliferating cells", not the verification of their pluripotency, and that both pages 22 and 45 of the specification refer the technique to the teaching of *Kaufman et al* and *Taylor et al. Kaufman et al* teach establishing pluripotent cell lines from mouse embryos, whereas *Taylor et al* teach that although the timing of developmental events is similar to that seen in fertilized oocytes, the

developmental potential of human parthenogenetic embryos was reduced, and the majority of those allowed to continue in co-culture arrested between the 2-cell, and 8-cell stages (abstract). *Taylor et al* is silent concerning whether these cells are capable of establishing as pluripotential stem cells. It is noted example 1(d) of the specification does refer to figures 10B-D, which are photos depicting blastocyst-like mass derived from human homozygous post-meiosis I diploid oocytes. However, the specification fails to teach whether such mass could be used for successfully establishing pluripotential stem cells. Accordingly, the specification and the cited references fail to support the assertion that human homozygous pluripotent stem cells are obtainable by the claimed method (from human parthenogenetic embryonic inner cell mass) so that a practical utility could be well established (see detailed discussion following). Therefore, the claimed method is not supported by a credible or well-established utility.

More impotently, it was indicated in the previous Office action that even if the human HS cells are obtainable, the only utility for establishing a cell depository is to carry out further research characterizing the homozygous stem cells, which is not considered as specific and substantial. Thus, the cell depository, thus, the method of establishing such has no specifically identified utility, rather, the specific utility of the HS cells requires further research to identify or reasonably confirm. (see Brenner, Comr. Pats. v. Manson, 148 USPQ 689 (US SupCt 1966). Applicants failed to address the rejection, thus for reasons of record and those set forth *supra*, the rejection stands.

Claims 29, 31, 32 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Specifically, since the claimed invention is not supported by either a credible asserted or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claims 29 and 31-33 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, for reasons of record and following.

In the response, Applicants argue that the specification has addressed the difficulty taught in the cited prior art, thus providing an enabling disclosure, and that human pluripotent stem cells could be obtained by the two other methods taught in the post-filing publication and the example of the specification.

In response, the previous Office action cited *Newman-Smith et al* (Development 1995;121:2069-77) and *Park et al* (Jpn J Vet Res 1998;46:19-28) because they both teach that stem cells obtained from parthenogenetic peri-implantation embryos are defective, and parthenogenetic embryonic stem cells retarded in growth and showed restricted differentiation compared to their fertilized counterpart (e.g. abstract), these teachings are consistent with the *Taylor* reference cited by the applicant. In the specification and the post-filing publication (Lin et al, Stem Cells 2003;21:152-61, IDS), applicants only show that "proliferating cells could be obtained and survived at least two passages", there is no showing the result of verification that the human proliferating cells are not defective and indeed pluripotent, i.e. capable of developing into three

layers, ectodermic, mesoderm, and endoderm as the mouse cells. Hence, the specification fails to provide evidence to the contrary of the cited art of record, and the response fails to address the issue raised in these references. Consistent with the above cited art, the Office action also cited *Draper et al* (Curr Opin Obstet Gynecol 2002;14:309-315) to indicated that it is well known in the art that human ES cells are distinct from mouse ES cells in many aspects. The instant disclosure fails to teach otherwise, thus, fails to provide an enabling disclosure for what is now claimed.

The response further fails to address the numerous barriers known in the art to use the HS cells for therapeutic purpose , (*Draper et al, Odorico et al, Donovan and Gearhart*), thus for reasons of record, the disclosure fails to provide an enabling guidance for the intended use of the HS cell depository.

Accordingly, in view of the limited guidance, the lack of predictability of the art and the breadth of the claims, one skill in the art could not practice the invention without undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 31-33 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is vague and indefinite because of the term "homozygous stem cells". In the response, applicants argue that according to the specification, the focus of the

invention is on the MHC, thus it is clear the claimed stem cells are homozygous with respect to MHC.

The argument has been fully considered but found not persuasive. This is because as noted in MPEP § 2111, claims must, under modern claim practice, stand alone to define invention. It is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See In re Paulsen, 30 F.3d 1475, 1480, 31 USPQ2d 1671 (Fed. Cir. 1994); Intervet America Inc. v Kee-Vet Lab. Inc., 887 F.2d 1050, 1053, 12 USP2d 1474, 1476 (Fed. Cir. 1989). Accordingly, the rejection stands.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Q. Janice Li** whose telephone number is 571-272-0730. The examiner can normally be reached on 9:30 am - 7 p.m., Monday through Friday, except every other Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Amy Nelson** can be reached on 571-272-0804. The fax numbers for the organization where this application or proceeding is assigned are **703-872-9306**.

Any inquiry of formal matters can be directed to the patent analyst, **Dianiece Jacobs**, whose telephone number is (571) 272-0532.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Q. Janice Li
Primary Examiner
Art Unit 1632

QJL
October 27, 2004